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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,218

04/25/2006

Geena Malhotra

TPP 31789

5437

77176

7590

04/23/2009

Novak, Druce & Quigg LLP  
1300 I Street, N.W.  
Suite 1000, West Tower  
WASHINGTON, DC 20005

EXAMINER

DOUGLAS, STEVEN O

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

04/23/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/562,218	<b>Applicant(s)</b> MALHOTRA ET AL.	
	<b>Examiner</b> /Steven O. Douglas/	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-9 and 11-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-9 and 11-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/23/05</u> .  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 3771

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,2 and 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jordan (GB 2 195 544).

The Jordan reference discloses a pharmaceutical inhaler that dispenses a metered dose comprising a canister made of a plastic material that is transparent and a metering valve, but fails to disclose the plastic material as being at least partially or entirely polycarbonate. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the plastic material be at least partially or entirely polycarbonate, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

In regard to claim 13, the Jordan reference discloses an inhaler (*supra*), but fails to disclose the canister as being made by injection molding or injection blow molding. Examiner takes Official Notice that injection molding and injection blow molding are commonly known methods of making containers in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the canister by either injection molding or injection blow molding in view of Examiner's Noticed observation of conventionality.

Art Unit: 3771

In regard to claims 14 and 15, the method as claimed would be inherent during normal use and operation of the device.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jordan (GB 2 195 544) in view of Morris, Jr.

The Jordan reference discloses a pharmaceutical dispenser (*supra*), but fails to disclose markings indicative of the amount remaining in the canister. The Morris, Jr. reference discloses another dispenser having markings 42 indicative of the amount of substance remaining in the dispensing container. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Jordan dispenser to include markings in view of the teachings of the Morris, Jr. reference to indicate the amount of substance remaining in the dispensing container.

Claims 7-9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jordan (GB 2 195 544) in view of Dickinson et al. (US 6,737,044).

The Jordan reference discloses a pharmaceutical dispenser (*supra*) including a broadly disclosed pharmaceutical formulation, but fails to disclose the formulation of the pharmaceutical being one of salbutamol, ipratropium and budesonide, and a propellant. The Dickinson et al. discloses another pharmaceutical dispenser including a formulation of the pharmaceutical being one of salbutamol, ipratropium and budesonide, and a propellant. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the pharmaceutical formulation as, for example, shown by Dickinson et al. for the broadly disclosed

Art Unit: 3771

formulation of Jordan wherein so doing would merely amount to the substitution of dispensed formulation for another that would work equally as well in the Jordan device.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Elliott et al. reference pertains to an inhaler device with a transparent canister.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Steven O. Douglas/ whose telephone number is (571) 272-4885. The examiner can normally be reached on Mon-Thurs 6:30-5:00.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3771

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven O. Douglas/  
Primary Examiner  
Art Unit 3771

SD  
4/22/09